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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,511	07/23/2004	Hirosige Nakatsuka	SAEGI15.002APC	5949
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KNOBBE MARTENS OLSON & BEAR LLP			THEXTON, MATTHEW	
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IRVINE, CA 92614			1714	

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/502,511	NAKATSUKA ET AL.	
	Examiner	Art Unit	
	Matthew A. Thexton	1714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2 and 5-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) 1,2 and 5-17 is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>one sheet</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Information Disclosure Statement

The non-patent literature citation has been lined through on the form PTO-1449 because it is not in the English language.

Claim Version

The claims as amended in the paper filed 2004 July 23 have been examined.

Claims Analysis

Claim 1 is directed to material...comprising at least one member from the group consisting of collagens, keratins, silk fibroins and their derivatives.

Dependent claims 5-9 further limit the amount of the member in the material, a physical property or physical shape or appearance of the material, its use in a cosmetic product, or an intended use as a "radiation-resistant medical or experimental material." Claims 8 and 9 state an intended use of "radiation-resistant medical or experimental material." Such is interpreted to encompass clothing worn by medical workers (doctors, dentists, chiropractors) and clothing worn by models which are experiments of design, as well as molded articles which may be employed in apparatus without limitation including medical, experimental, measuring, and household.

Claim 13 depends from claim 1 and are directed to methods comprising "protecting a subject with a radioprotective materials according to claim 1." Claims 14-17 depend from claim 13 and further require: the member "is administered to, mixed

with, coated on or immobilized on a subject," a product comprising the member "is used to protect a subject," a product comprising the member "is placed over, applied to or administered to a subject," or that the member "is present inside a subject or inside a surface layer of a subject in a total amount of 0.05 wt.% to 40 wt%."

Independent claim 2 is directed to material comprising at least one member selected from the group consisting of collagens and their derivatives.

Independent claim 10 is directed to methods comprising "adding" at least one component from the group consisting of collagens, keratins, silk fibroins and their derivatives to a product "to render the product radioprotective."

Independent claim 11 is directed to methods comprising "adding" at least one component from the group consisting of collagens, keratins, silk fibroins and their derivatives to a material "to produce a radioprotective material."

Independent claim 12 is directed to methods comprising "adding" at least one component from the group consisting of collagens, keratins, silk fibroins and their derivatives to a material "to produce a radioprotective material in a desired shape."

Claims 3 and 4 have been canceled.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

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dependent form, or rewrite the claim(s) in independent form. There is no difference between a radioprotective product and a radioprotective material.

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. There is no difference between a radioprotective product and a radioprotective preparation.

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. There is no difference between a radioprotective material and a radioprotective product.

Double Patenting

Applicant is advised that should claim 8 be found allowable, claim 8 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Applicant is advised that should claim 10 be found allowable, claim 11 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two

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claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim.

See MPEP § 706.03(k).

35 USC § 102 and 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections

Claims 1, 2, and 5-17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Official Notice of commercially available materials comprising collagen, keratin, or silk.

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

Claim 1 encompasses the single material comprising silk fibroins; such is fully anticipated by silk. Radioprotective property is inherent and overtly ongoing.

Claim 2 encompasses the single material or mixtures containing collagen; such is fully anticipated by animal glue and gelatin. Radioprotective property is inherent and overtly ongoing.

Claims 5-9 depend directly or indirectly upon claim 1. Each claim encompasses clothing made from blends of silk and non-silk (such as rayon, cotton, linen). Radioprotective property is inherent and overtly ongoing. Claims 8 and 9 state an intended use of "radiation-resistant medical or experimental material." Such is interpreted to encompass clothing worn by medical workers (doctors, dentists, chiropractors) and clothing worn by models which are experiments of design.

Claims 10-12 encompass weaving silk and non-silk fibers to make textiles. Radioprotective property is inherent.

Claims 13-17 encompass wearing a clothing made from blends of silk and non-silk (such as rayon, cotton, linen). Radioprotective property is inherent.

Claims 1, 2, and 5-17 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Pauly et al. (WO 01/45661-A2, as evidenced by US 2003/0091518-A1). All references to this document will be to the US version, aka '518.

The present claims are broadly discussed hereinabove in the section **Claims Analysis** which is incorporated by reference.

Reference '518 discloses that protection from harmful rays of the sun may be obtained by antioxidants including amino acids and peptides (paragraph 59). Various examples of cosmetics are set forth which employ forms of keratin and collagen (examples 4, 7-9, 11, 16, 18-20, 25, 27). Proportions are encompassed by claims 6 and 17. Radioprotective property is inherent and overtly ongoing.

Claims 1 and 5-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Urita (JP 10-338615-A, as evidenced by Applicant submitted abstract). A translation of this reference has been requested and will be forwarded when received.

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

Reference '615 discloses that protection from harmful rays of the sun may be obtained by forming cosmetics containing a derivative of tussah (type of silkworm) fibroin. Radioprotective property is inherent and overtly ongoing.

In the event the reference is deemed to be of not sufficient specificity to sustain a conclusion of anticipation, such as with respect to the proportions of claims 6 and 17, then it is concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to have varied the proportions to accomplish the protection suggested.

Claims 1, 2, and 5-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Natsume et al. (JP 01-280465-A, as evidenced by Applicant submitted abstract). A translation of this reference has been requested and will be forwarded when received.

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

Reference '465 discloses materials containing a derivative of collagen, which may be used for suturing. Radioprotective property is inherent and overtly ongoing.

In the event the reference is deemed to be of not sufficient specificity to sustain a conclusion of anticipation, such as with respect to the proportions of claims 6 and 17, then it is concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to have varied the proportions for reasons of economy.

Claims 1, 2, and 5-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Erwin (US 4946450).

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

Reference '450 discloses materials containing collagen, which may be used for therapeutic eye shield. Radioprotective property is inherent and overtly ongoing.

In the event the reference is deemed to be of not sufficient specificity to sustain a conclusion of anticipation, such as with respect to the proportions of claims 6 and 17, then it is concluded that it would have been obvious to one of ordinary skill in the art at

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the time of the invention to have varied the proportions since '450 suggests "about 50 %" which is reasonably close to 40%.

Claims 1, 2, and 5-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sano et al. (US 5718954-A).

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

Reference '954 discloses materials containing powdered collagen, powdered silk, powdered wool, keratin fine powder (column 3, lines 45-49, column 5, lines 25-29, claims 1-25). The materials may comprise polymers and paints which may be formed into objects, laminated with cloth, spun into fibers which may be used for cloth, used to treat clothing and other surfaces. Proportion suggestions for uses are set forth and are encompassed by Applicant's claims. Specific examples employ collagen (1-5, 10, 12, 17-20), silk (6, 14, 15, 21-54), wool (8). Radioprotective property is inherent and overtly ongoing.

In the event the reference is deemed to be of not sufficient specificity to sustain a conclusion of anticipation, then it is concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to have varied the additives following the suggestions of the reference and thus arrive at subject matter encompassed by the claims.

Claims 1, 2, and 5-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sakaki et al. (US 5587411-A).

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

Reference '411 discloses rubber materials containing powdered protein such as keratin (examples 1-9). The materials may be formed into objects such as artificial organs, gloves, condoms, and catheters (column 4, lines 9-12). Proportion suggestions for uses are set forth and are encompassed by Applicant's claims. Radioprotective property is inherent and overtly ongoing.

Since collagen is not specifically suggested, claim 2 is rejected as obvious in view of the suggestion to employ proteins that have a lot of SH groups (column 2, lines 53-58).

In the event the reference is deemed to be of not sufficient specificity to sustain a conclusion of anticipation, then it is concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to have varied the additives following the suggestions of the reference and thus arrive at subject matter encompassed by the claims.

Claims 1, 2, and 5-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sato et al. (US 4638024).

The present claims are broadly discussed hereinabove in the section ***Claims Analysis*** which is incorporated by reference.

Reference '024 discloses polymer materials containing protein such as gelatin, or glue (keratin is a main constituent of protein-based glues). The materials may be used in products relating to food and medicines (column 1, lines 42-46) and photographic emulsions, microcapsules, paper processing agent, or fiber treating agent (column 5 line 54 to column 6 line 2). Microcapsules are construed to be a medicine application. Proportion suggestions for uses are set forth and are encompassed by Applicant's claims. Radioprotective property is inherent and overtly ongoing.

Since collagen is not preferred for paper processing or fiber treating, claim 14 is rejected as obvious in view of the suggestion that gelatin may be used even though casein is preferred.

In the event the reference is deemed to be of not sufficient specificity to sustain a conclusion of anticipation, then it is concluded that it would have been obvious to one of ordinary skill in the art at the time of the invention to have varied the additives following the suggestions of the reference and thus arrive at subject matter encompassed by the claims.

Conclusion

It is well established in case law that the discovery of a "new" property does not usually lend patentability to an otherwise old or obvious compound or composition.

Citation of Pertinent Prior Art

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Urita (JP 09-241399-A), cited by Applicant, appears to be cumulative to the disclosure of Urita (JP 10-338615-A) which is relied upon hereinabove for a prior art rejection.

Nosov et al. (EP 1020874 A1) is thought to be an English language equivalent to WO 99/17303, cited by Applicant, and is cited to complete the record.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew A. Thexton whose telephone number is 571-272-1125. The examiner can normally be reached on Monday-Friday, 9:30 to 6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasudevan S. Jagannathan can be reached on 571-272-1119. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

M. A. Thexton

Matthew A. Thexton
Primary Examiner
Art Unit 1714